UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA

ROBERT H. ODELL JR., M.D., PH.D.,
ROBERT ODELL M.D. PH.D. MEDICAL ENTERPRISES,
A Nevada Corporation
And
JOHN DOE, an individual Sui Juris,

Plaintiffs,

v. **Case No.**

SYLVIA MATHEWS BURWELL
In her Official Capacity as
Secretary of Health and Human Services;
UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES (HHS);
NORIDIAN HEALTHCARE SOLUTIONS, L.L.C.,

Defendants.

VERIFIED COMPLAINT FOR INJUCTIVE RELIEF, WRIT OF MANDAMUS, JUDICIAL REVIEW, AND OTHER RELIEF.

Robert H. Odell Jr., M.D., Ph.D., individually, Robert Odell M.D. Ph.D., Medical Enterprises, a Nevada Corporation, referred to by their proper name or collectively as "Plaintiffs Odell", and John Doe, individually, by and through their undersigned attorney, brings this action against Sylvia Mathews Burwell, in her official capacity as Secretary of Health and Human Services, hereinafter referred to as "Secretary", the United States Department of Health and Human Services (HHS), and Noridian Healthcare Solutions, LLC., hereinafter referred to as "Noridian", and states as follows:

PRELIMINARY STATEMENT

1. The Medicare program has been refusing to reimburse Plaintiffs, Odell, for thousands of dollars' worth of care provided to patients, even though the care provided was reasonable and medically necessary as the Medicare Act requires. The government's refusal to pay for this care is harming Dr. Odell's patients and medical practice. The government's refusal to make payment violates the Medicare Act, is arbitrary and capricious, and is otherwise unlawful and unconstitutional. Plaintiff, John Doe, is a Medicare beneficiary who has received reasonable and necessary medical care and service from Plaintiffs Odell and Defendants have refused to reimburse for this care as the Medicare Act requires. Plaintiffs seek a declaration to that effect, a writ of Mandamus, as well as monetary and other relief.

2. The Centers for Medicare and Medicaid services (CMS) employ private for profit Contractors known as Medicare Administrative Contractors (MAC) to administer the program on the regional level.

3. The MAC develop and apply Medicare Local Coverage Determinations (LCD) and establish Medicare coverage policies for reimbursement.

4. As will be described supra, the local MAC develops and/or applies LCDs depriving Medicare beneficiaries of medically reasonable and necessary services and will continue to do so unless declared invalid and enjoined by the court.

5. When a patient comes to a medical clinic for treatment, the decision as to what treatment to render is based upon the expert judgement of the attending physician.

6. After receiving Medicare bills, the CMS acting through regional contractors will often routinely classify medical treatment as medically unnecessary and thereby refuse reimbursement to medical providers. The provider may then request a redetermination of the

denial from the same regional CMS contractor. Thereafter, a provider can appeal an unfavorable redetermination for reconsideration. If the reconsideration is adverse, the provider may seek a hearing before an administrative law judge appointed through the Department of Health and Human Services Office of Medicare Hearings and Appeals.

7. Plaintiffs Odell routinely use a combined electro-chemical treatment for neurological ischemia that is a root cause of pain, numbness and loss of functionality in the lower extremities. Plaintiffs Odell have successfully treated hundreds of patients resulting in restoring functionality of the patients lower extremities.

8. Plaintiff, John Doe, is a Medicare beneficiary who was significantly impaired with pain, numbness, and a loss of functionality in his lower extremities. Plaintiff, John Doe, received the combined electro-chemical treatment from Doctors Odell and recovered functionality in his lower extremities.

9. Defendants are now denying reimbursement and have wrongfully recovered reimbursement previously paid by misapplying an LCD that does apply to the treatment rendered by the Plaintiff.

10. Plaintiffs Odell have successfully appealed several refusals to reimburse by the government for the exact same treatment for the same conditions. These appeals have resulted in a multitude of favorable decisions rendered by ALJ's appointed by HHS. The most recent administrative law judge decision was rendered August 30, 2013. *ALJ Appeal Nos: 1-1211937301 and 14 others before Stuart A. Wein US Administrative Law Judge*. This successful decision was not appealed by the CMS contractor who was party to the action. The ALJ decision finds the treatment rendered by Plaintiff to several beneficiaries described therein to be medically necessary and reimbursable under the Medicare Act.

11. Plaintiff has received the following favorable decisions from Administrative Law Judges appointed by the Defendant confirming medical necessity for the same treatment he has repeatedly rendered and reversing the Medicare Contractors repeated improper application of LCD L28271 to deny reimbursement. These favorable decisions are listed as follows:

	Patient Initials	Medicare Appeal#
1.	S.P	1-787013612
2.	G.T	1-171021882
3.	H.E.	1-787021692
4.	R.C.	1-778027862
5.	H.E.	1-787018192
6.	R.H.	1-787020962
7.	W.M.	1-787021122
8.	T.S.	1-787020012
9.	S.P.	1-787013292
10.	W.M	1-787020162
11.	W.M.	1-787013082
12.	J.N.	1-787001722
13.	R.I.	1-823373132
14.	S.J.	1-823378258
15.	J.L.	1-823378778
16.	T.M.	1-823378877
17.	D.C.	1-82372286
18.	D.C.	1-823526180

19.	H.E.	1-823372676
20.	T.B.	1-823332081
21.	H.D.	1-823372484
22.	H.D.	1-823372570
23.	C.T.	1-823573546
24.	S.P.	1-823525924
25.	P.O.	1-823378929
26.	R.C.	1-823356886
27.	B.L.	1-823378424
28.	R.I.	1-911197922
29.	S.J.	1-911297101
30.	J.L.	1-911154561
31.	T.M.	1-911154778
32.	D.C.	1-911317364
33.	D.C.	1-911297245
34.	T.B.	1-915200781
35.	H.D.	1-911305674
36.	H.D.	1-911306047
37.	C.T.	1-911053951
38.	P.O.	1-911155125
39.	R.C.	1-911318225
40.	B.L.	1-911080482
41.	R.I.	1-1212116803

42.	S.J.	1-1212133299
43.	J.L.	1-1212174326
44.	T.M.	1-1212191364
45.	D.C.	1-1212015369
46.	D.C.	1-1212044614
47.	H.E.	1-1212096268
48.	T.B.	1-1211937301
49.	H.D.	1-1212055259
50.	H.D.	1-1212084343
51.	C.T	1-1212244004
52.	S.P.	1-1212234248
53.	P.O.	1-1212213904

12. Despite the favorable ALJ decisions cited and the lack of any appeal by the regional CMS contractor, the government continues to refuse to reimburse Plaintiffs Odell and has systematically recovered monies paid on the basis of the same local coverage determination found repeatedly to be inapplicable by the multiple ALJ decisions cited. Plaintiffs Odell have made demand upon CMS to abide by the ALJ decisions and it has continuously refused. The lack of an appeal by the CMS contractor results in the ALJ decisions becoming binding upon the parties thereto. *42 CFR 405.1098.*

13. The ALJ decision of Judge Wein specifically held that the government contractors' reliance upon LCD L28271 for denying the claims was improper. Further, the ALJ decisions found that the LCD L28240 cited by Plaintiff was the correct LCD and the same did allow for payment of the claims billed under CPT code 64450. Id.

14. Recently, the Secretary of Health and Human Services (HHS), charged with administering the Medicare Act through the Centers for Medicare and Medicaid services (CMS) has begun employing independent third party Recovery Audit Contractors (RACs) to review physicians decisions. These RACs are private third parties who are paid a percentage of the amount they can take back from physician's clinics and hospitals. These RACs will overrule physician's decisions as to the medical necessity of treatment without having reviewed any of the medical records or having interviewed the patients or physicians.

15. Not only has CMS refused to reimburse Plaintiffs Odell according to the ALJ decisions for the treatment rendered, they have subsequently engaged in serial RAC audits resulting in repeated denials of claims for reimbursement for the exact same services deemed medically necessary by the ALJ decisions. These RAC audits find no medical necessity without any review of the medical record nor any contact with the provider or patient. In these denials for reimbursement the MAC continuously and explicitly cites LCD L28271 as grounds to recover amounts properly billed and paid.

16. Pursuant to the serial RAC audits, the government has seized reimbursement paid to Plaintiff through the process of Recoupment. In effect the government is paying a current claim for the exact same services and then seizing this reimbursement payment in recoupment for past claims they now classify as not medically necessary pursuant to LCD 28271.

17. As the same provider for virtually the same services, Plaintiff is entitled by law to be treated consistently in accordance with the Administrative decisions and not in a completely arbitrary and capricious manner.

18. The government has not and cannot, articulate any reasons for declaring every procedure audited or billed not medically necessary without any review of the individual patients medical record.

19. Pursuant to 42 USC 1879, Plaintiffs are entitled to reimbursement under the Medicare Act for services rendered to beneficiaries when they did not "know or could not reasonably been expected to know" that payment would be denied. Id. Defendants are denying reimbursement pursuant to this section by expressly stating Plaintiffs should have known that LCD L28271 bars reimbursement.

20. Despite multiple ALJ decisions in favor of Plaintiff Odell finding LCD L28271 to be inapplicable to the services he has rendered, Defendants continue to site the same LCD as a basis to claim Dr. Odell should have known no reimbursement would be forthcoming and therefor are denying reimbursement properly due to Plaintiffs pursuant to 42 USC §1879.

21. Plaintiff, John Doe, is a 75 year old Medicare beneficiary who resides in Nevada. He is using the pseudonym "John Doe" to protect his confidential health information. John Doe is a Medicare Part B enrollee who suffers chronic conditions in his lower extremities which caused a loss of function and which have been significantly improved by the administration of medication and physician services all of which have been prescribed by his physician, Plaintiff, Robert Odell, Jr., M.D.

22. The unlawful recoupment and failure to pay funds, together with the repeated disruption of all billing through serial RAC audits has resulted in the closure of medical offices belonging to plaintiff thereby denying patients medically necessary care and causing serious financial harm to Plaintiff. Furthermore, future planning is rendered impossible by the repeated disruptions in billing. Plaintiffs Odell have suffered and will continue to suffer irreparable harm

as a result of the governments arbitrary treatment in the form of closure of Plaintiffs Odell's medical practice and the ongoing seizure of reimbursement due Plaintiffs.

PARTIES

23. Defendants are denying reimbursement for the care and treatment rendered to John Doe and all similar claims for lack of medical necessity without reviewing any medical records. The government has instituted an unwritten policy of denying Plaintiffs Odell's claims. (The "Unwritten Policy").

24. Plaintiff, John Doe, has learned that Medicare will not cover or pay for these medications and services because of the Unwritten Policy described herein. This non-coverage policy jeopardizes Mr. Doe and similarly situated Part B enrollees access to medically necessary services.

25. Plaintiff, Robert H. Odell, Jr., M.D., individually, is a medical doctor licensed to practice medicine in the state of Nevada.

26. Plaintiff, Robert Odell M.D. Ph.D. Medical Enterprises, is a Nevada corporation organized and existing under the corporation laws of the State of Nevada. Robert Odell M.D. Ph.D. Medical Enterprises is and has been at all relevant times, a participating and approved provider of medical services under assignment pursuant to Part B of the Medicare program.

27. Defendant, Sylvia Mathews Burwell, is an officer of the government of the United States and is named in her official capacity as the Secretary of the United States Department of Health and Human Services ("Secretary"), the agency of the United States government designed by Congress to implement and enforce the Medicare Act, 42 U.S. C. 1395, et seq., and specifically 42 U.S.C. 1395m, and regulations promulgated by the Secretary, including but not limited to 42 C.F.R. 410.26 et seq., designed to implement and enforce the aforesaid statutory

provisions. The Secretary is subject to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551, et. Seq. The actions, errors, and omissions of the Secretary, at all times relevant to this litigation, constitute federal governmental action subject to the Fifth Amendment to the United States Constitution.

28. Defendant United States Department of Health and Human Services (HHS) is an Agency of the government of the United States designed by Congress to implement and enforce the Medicare Act, 42 U.S.C. 1395, et. Seq., and specifically 42 U.S.C. 1395m and regulations promulgated by the Secretary, including but not limited to, 42 C.F.R. 410.36 et seq. HHS is subject to the provisions of the APA, 5 U.S.C. 551. Et seq. The Centers for Medicare and Medicaid Services (CMS) is the subdivision of HHS which oversees Medicare program. The actions, errors and omissions of HHS, at all times relevant to this litigation, constitute federal governmental action subject to the Fifth Amendment to the United States Constitution.

29. Defendant Noridian Healthcare Solutions LLC., is a for profit corporation. Noridian is now and at all times relevant to this litigation, has been under contract with the Secretary and HHS to administer the Medicare program in Nevada.

JURISDICTION AND VENUE

30. This action arises under the Social Security Act, 42 U.S.C. 1301, et seq., implicating the Medicare Act, 42 U.S.C. 1395, et seq., and the Medicaid Act, 42 U.S.C. 1396 et seq., as well as the Fifth Amendment to the United States Constitution.

31. This Court has original jurisdiction over this civil action for a case involving a federal question pursuant to 28 U.S.C. 1331, for a mandamus action to compel an officer of the United States to perform her duties pursuant to 28 U.S.C. 1361, for prohibition against federal interference against the exercise of control over the administration or operation of any institution,

agency or person, pursuant to 28 U.S.C.1651, and pursuant to 42 U.S.C. 1395, and the Court's general equity powers.

32. Jurisdiction is also based upon the judicial review of the Administrative Procedure Act (APA), 5 U.S.C. 551 and 706(2), 28 U.S.C. 1361, and 42 U.S.C. 1395 et seq.

33. Jurisdiction is also based upon 42 U.S.C. 405(g) which provides the basis for the Court's jurisdiction over Plaintiffs' claims that challenge the underlying Medicare/Medicaid appeal. Section 405(g) applies to the Medicare Act through 42 U.S.C. 1395ff(b)(1)(A) and provides that the United States District Court "shall have the power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the [Secretary] with, or without remanding the cause for a rehearing." 42 U.S.C. 405(g).

34. Plaintiffs Odell and John Doe reside or conduct business and have offices located in Las Vegas, Nevada. Thus, venue is proper in the District of Nevada pursuant to 28 U.S.C. 1391(e) and 42 U.S.C. 1395oo(f).

STATUTES AND REGULATIONS

35. The Social Security Act provides coverage for medical and other health services to the aged and disabled otherwise known as Medicare. 42 U.S.C. § 1395 *et seq.*

36. Beneficiaries of the Medicare Part B program are entitled to have payments made to him/her or on their behalf for medical and other covered health services. Social Security Act Section 1832 (a)(1) and 42 C.F.R. Section 410.4 (a)(1).

37. The Medicare Act requires services to be "reasonable and necessary for the diagnosis and treatment of illness or injury, or to improve the functioning of a malformed body member. Id Section 1395y(a).

38. The very first provision of the Medicare Act prohibits the government from exercising any control over the practice of medicine or the manner in which medical services are provided through the Medicare program. 42 U.S.C. Section 1395.

39. The RAC typically conduct their audits by reviewing billing records only and opining on the propriety of treatment decisions. The RAC receive payment for their auditing services on a contingent basis; the more money they recover from "improper payments" to providers, the more RACs stand to benefit financially.

40. Congress made the program permanent in 2006. *See* Pub. L. No. 109-432. 120 Stat. 292 (2006), codified at 42 U.S.C. § 1395ddd.

41. The RAC Program has been considered a "success" for CMS and the RACs: RACs collected $1.86 billion in overpayments from October 2009 through March 2012. Over that same time period, RACs identified only $245.2 million in underpayments. CMS, *Medicare Fee-for-Service Recovery Audit Program, May 2012*, 1 (*"May 2012 Report"*). The funds recovered were taken from medical providers who have already rendered medical services to Medicare beneficiaries.

42. The RACs are quite frequently wrong in their assertions about what a physician, confronted with a patient in need of medical treatment, should have done months or years earlier.

43. Despite Plaintiffs Odell's continued success in overturning the denial of claims, CMS has instituted the Unwritten Policy routinely denying claims submitted by Plaintiffs Odell under billing code CPT 64450 or recouping funds previously paid for claims identical to claims previously appealed and found to be medically necessary on repeated occasions by ALJ's appointed by the government. The government routinely relies on the same LCD L28271 to deny

the claim that has been repeatedly found to be inapplicable dozens of times over by ALJ opinion after ALJ opinion.

44. MACs engage in rule making through the institution of Local Coverage Determinations (LCD's). 42 USC 1395 KK-1(a). These LCD's provide guidance to providers as to what medical services said contractor deems reimbursable. Noridian LLC is the MAC for Nevada.

45. The government is forbidden under section 1871 (a)(2) Social Security Act from establishing substantive legal standards governing payment for services under the Medicare Program unless promulgated as a regulation.

46. The Chief ALJ for this process recently put a minimum two year hold on the ALJ process due to a backlog of Medicare appeals. *See* Memo from Office of Medicare Hearing & Appeals, to Medicare Appellants (Dec. 24, 2013). Thus, it will be years before a provider can even attempt to avoid the application (or misapplication) of an adverse LCD for a claim for medical services ordered by a doctor today for a Medicare patient. Plaintiff currently has administrative appeals pending and will be filing additional appeals, which will be adversely affected by the delay caused by the two-year old hold on ALJ appeals.

47. The government, through its regional contractor, Noridian and through RACs, has routinely denying claims submitted by Plaintiffs Odell long before finalizing a proposed LCD directed to this specific type of claim.

48. Noridian has now issued a new LCD which attempts to address (but itself is inapplicable) the medical services routinely provided by Plaintiff and which have been routinely found to be medically necessary by ALJ decisions. The development of a new LCD implicitly acknowledges that LCD 28271 repeatedly used to recoup or deny was not applicable.

49. Medicare's actions pose imminent, irreparable harm to Plaintiffs Odell and Plaintiff, John Doe.

50. As a result, the wrongful Medicare denial results in a significant loss of revenue to Plaintiffs Odell.

51. Plaintiff seeks reasonable and necessary attorney's fees and costs as provided by 28 U.S.C. 2412.

COUNT I WRIT OF MANDAMUS

Plaintiffs repeat and re-allege paragraphs 1- 51 as if set forth fully herein.

52. Under 28 U.S.C. § 1361, "[t]he district court shall have original jurisdiction of any action in the nature of mandamus to compel an officer of employee of the United States or any agency thereof to perform duty owed to the Plaintiff".

53. The defendant owes all sums due pursuant to the ALJ decisions that are binding between the parties due to a lack of an appeal.

54. Plaintiffs Odell are owed reimbursement from defendant for the claims found to be medically necessary and reimbursable.

55. Plaintiffs Odell are owed all sums that have been recouped or seized based upon the Unwritten Policy.

56. Plaintiff, John Doe, will be denied future medical care and treatment he is entitled to under the Medicare Act if Defendants do not perform their legal duties.

57. Noridian must perform its duties pursuant to legal authority. See, 42 U.S.C. 1395kk-1(b)(2). Mandamus relief should be issued here where (1) Plaintiffs have a clear right to relief; (2) Noridian has a clear right to act; and (3) no other adequate remedy exists. Wolcott v. Sebelius, 635 F.3d 757, 768 (5th Cir. 2011). Here, Plaintiffs challenged Noridian's

misapplication of an LCD and unwritten policy. The Administrative Law Judge ruled in favor of the Plaintiffs. Faced with the appellate challenge, Noridian revised its LCD.

58. Noridian was bound by law not to exclude the Plaintiffs' medical services from Medicare. 42 C.F.R. 426.420(b), 424.460(b), 426.463. Noridian has no discretion to arbitrarily deny Plaintiff's claims without cause. 42 C.F.R. 426.420(b), 4 24.460(b), 426.463; see also, 68 Fed.Reg. 63692-01. Instead, Noridian has a non-discretionary duty to perform its obligations under law, which is to maintain the status quo, and utilize the proper coverage criteria recognized by the Administrative Law Judge.

59. Plaintiffs have no adequate remedy at law. Noridian simply ignores the binding effect of Plaintiffs repeated and successful challenges to the misapplication of LCD L28271. Plaintiffs cannot administratively challenge Noridian's arbitrary and capricious action of misapplying an LCD to preclude Medicare coverage. Noridian's arbitrary and capricious decision to deny coverage must be set aside.

60. Plaintiffs request that this Honorable Court protect the Medicare patients and compel Noridian to following the administrative law judge's opinions finding Plaintiffs' medical treatment to be medically reasonable and necessary and order that Medicare reimburse Plaintiffs.

COUNT TWO: INJUNCTIVE RELIEF

Plaintiffs hereby incorporate by reference Paragraphs 1 to 51 herein.

61. As alleged above, Noridian has no discretion to misapply its non-coverage LCD absent evidence additional to that previously relied on by Noridian to support non-coverage. Noridian has not provided any additional basis on which to apply the non-coverage LCD. The Court must restrain Noridian from continuing to misapply a non-coverage LCD that was the subject in fact of multiple challenges.

62. A party seeking a preliminary restraining order or a preliminary injunction must prove each of the following elements: (1) that there is a substantial likelihood that the movant will prevail on the merits; (2) that there is a substantial threat that irreparable harm will result if the injunction is not granted; (3) that the threatened injury outweighs the threatened harm to the defendant; and (4) that the granting of the preliminary injunction will not disserve the public interest. Clark v. Prichard, 812 F.2d 991, 993 (5th Cir. 1987); see also, Janvey v. Algutre, 647 F.3d 585, 595 (5th Cir. 2011); DeWall Enterprizes, Inc., 2006 F.Supp.2d at 1000-01, Fed. R. Civ. P. 65(b).

63. Plaintiffs have demonstrated a likelihood of success on the merits by Noridian's action of ignoring the Administrative Law Judge decisions and misapplying its LCD in the face of a challenge. Noridian has provided no justification for ignoring the ALJ's decisions as it is required to do so. See 42 C.F.R. 426.420(b), 424.460(b), 426.463; See also, 68 Fed. Reg. 63692-0. Further, numerous ALJ's have found the medical services rendered by Plaintiffs Odell to be a procedure covered by Medicare, provided it is reasonable and necessary for the particular patient beneficiary.

64. Plaintiffs are irreparably harmed by the wrongful Medicare coverage denials. Plaintiffs Odell will lose substantial income from a blanket denial of Medicare coverage. The wrongful denials results in lost income.

65. The threatened injury to Plaintiffs Odell outweighs the threatened harm to Noridian. Plaintiffs are only asking the Court to require Noridian to follow the procedures that preclude Noridian from using the wrong LCD. Plaintiffs Odell are requesting that Court order Noridian to follow the law. 42 C.F.R. 426.420(b), 424.460(b), 426.463.

66. Accordingly, upon hearing, Plaintiffs Odell request that a temporary restraining order be posted and remain in effect until such time as a temporary injunction can be entered to protect Plaintiffs' interest, which enjoins Noridian, its officers, agents, servants, employees, attorneys, and all other persons acting in concert or participation with any of them who received actual notice of the order by personal service or otherwise from imposing an LCD that categorically denies Medicare coverage of Plaintiffs Odell's services.

COUNT THREE: VIOLATION OF PROCEDURAL DUE PROCESS

Plaintiffs reassert and incorporate by reference paragraphs 1 – 51 herein.

67. Medicare offers no administrative channel to meaningfully challenge the repeated misapplication of an LCD as conducted by Noridian in the instant case. As a result, the channeling requirement, if applied, does not simply post-pone judicial review, it precludes that review. This violates the United States constitution's Fifth Amendment Due Process Clause.

COUNT FOUR: VIOLATION OF ADMINISTRATIVE PROCEDURE ACT

(The CMS Unwritten Policy Is Not Accordance with the Medicare Act)

Plaintiffs reassert and incorporate by reference paragraphs 1 – 51 herein.

68. The Medicare Act entitle[s] Plaintiffs Odell to payment for all reasonable and necessary medical and other health services provided to beneficiaries, 42 U.S.C. § 1395k(a)(2), except for services the statute specifically excludes, see id § 1395y.

69. The services provided by Plaintiffs Odell in this case are reasonable and medically necessary medical and other health services that do not fall within a statutory exclusion.

70. CMS's Unwritten Policy prohibiting Part B payment for reasonable and medically necessary items and services is invalid under the APA because it violates the Medicare Act.

71. The Secretary must direct CMS to reimburse Plaintiffs Odell under Part B for the medically necessary and reasonable care provided.

COUNT FIVE: VIOLATION OF ADMINISTRATIVE PROCEDURE ACT

(The CMS Unwritten Policy is Arbitrary and Capricious)

Plaintiffs reassert and incorporate by reference paragraphs 1 through 49 above as though fully set forth herein.

72. The APA prohibits Defendant from implementing the Medicare Act via actions, findings, or conclusions that are arbitrary and capricious. 5 U.S.C. § 706(2)(A).

73. Plaintiffs do not believe it is possible for CMS to articulate a satisfactory explanation for the Unwritten Policy. Nonetheless, CMS's failure to articulate any reasonable explanation for refusing to reimburse or recouping amounts previously paid Plaintiff for services that have routinely been found reasonable and medically necessary renders the Unwritten Policy arbitrary and capricious and thus invalid under the APA.

74. CMS's failure to articulate a satisfactory explanation-or any explanation-for refusing Plaintiffs claims, renders CMS's Unwritten Policy arbitrary and capricious and thus invalid under the APA.

COUNT SIX: VIOLATION OF ADMINISTRATIVE PROCEDURE ACT

(CMS's Failure to Follow Precedent is Arbitrary and Capricious)

Plaintiffs reassert and incorporate by reference paragraphs 1 – 51 herein.

75. The APA prohibits Defendants from implementing the Medicare Act via actions, findings, or conclusions that are arbitrary and capricious. 5 U.S.C. § 706(2)(A).

76. An agency action is arbitrary and capricious if it departs from agency precedent without explanation.

77. Defendant continues to enforce the Unwritten Policy even though she repeatedly has found that Part B payment is warranted for reasonable and medically necessary items and services provided in these Part B denial cases.

78. By continuing to enforce the Unwritten Policy, Defendants have acted arbitrarily and capriciously in violation of the APA.

COUNT SEVEN: VIOLATION OF ADMINISTRATIVE PROCEDURE ACT

(The CMS Unwritten Policy is Invalid for Failure to Undergo Notice)

Plaintiffs reassert and incorporate by reference paragraphs 1 – 51 herein.

79. The APA prohibits Defendants from implementing the Medicare Act via actions, findings, or conclusions accomplished without observing the procedures require by law. 5 U.S.C. § 706(2)(A).

80. The APA requires agencies to afford notice of a proposed rule-making and an opportunity for public comment prior to a rule's promulgation, amendment, modification, or repeal. Id § 553.

81. The APA's notice-and-comment requirements do not apply to certain interpretive rules, general statements of policy, or rules of general agency organization, procedure or practice. See id. The Unwritten Policy does not fall within any of those categories. Nor has Defendant articulated good cause for failing to submit the Unwritten Policy to notice and public comment.

82. To comport with the mandates of the APA, Defendants therefore must have subjected the Unwritten Policy to notice and comment procedures.

83. Defendants did not subject the Unwritten Policy to notice and comment procedures.

84. Defendant's failure to do so violates the APA.

85. This failure constitutes a separate reason why the Unwritten Policy is invalid. To be clear: The policy would be unlawful no matter the procedures used to promulgate it because it conflicts with the Medicare statute and because it is arbitrary and capricious. But even setting aside these fatal problems, the Unwritten Policy cannot stand under the APA.

COUNT EIGHT: VIOLATION OF MEDICARE ACT

(The CMS Unwritten Policy is Invalid Because It Was Not Promulgated as a Regulation)

Plaintiffs reassert and incorporate by reference paragraphs 1 – 51 herein.

86. The Medicare Act requires that all rules, requirements, and statements of policy that establish or change a substantive legal standard governing the scope of benefits or payment for services be promulgated via regulation. 42 U.S.C. § 1395hh(a).

87. CMS's Unwritten Policy establishes a substantive legal standard governing the scope of Part B benefits and payment for items and services.

88. Defendant did not promulgate the Unwritten Policy as a regulation.

89. Defendant's failure to do so violated the Medicare Act.

90. The Unwritten Policy would be invalid even if promulgated as a regulation, because it cannot be reconciled with the Medicare statute and because it is arbitrary and capricious. The failure to promulgate the Policy as a regulation nonetheless constitutes an additional independent reason why the Policy cannot stand.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests that this Court issue judgement in their favor and against Defendant and issue the following relief:

A. A declaratory judgement that CMS's Unwritten Policy is invalid because it violates the language and purpose of the Medicare Act.

B. A declaratory judgement that CMS's Unwritten Policy is arbitrary and capricious because Defendant has not articulated a satisfactory explanation for refusing to reimburse providers for reasonable and medically necessary services provided;

C. A declaratory judgement that CMS's Unwritten Denial Policy is invalid under the APA for failure to undergo notice and comment rulemaking;

D. A declaratory judgement that CMS's Unwritten Policy is invalid under the Medicare Act because it was not promulgated as regulation;

E. A declaratory judgement that CMS's Unwritten Policy is arbitrary and capricious because Defendant has not provided an explanation for departing from, and refusing to adhere to, her final decisions in prior appeals awarding Part B payment;

F. A Writ of Mandamus requiring Defendant to return all sums unlawfully recouped from Plaintiff.

G. An order vacating or setting aside CMS's Unwritten Policy;

H. An order that the Plaintiff be paid full Part B reimbursement for the claims recouped or seized pursuant to the Unwritten Policy;

I. Reimbursement for all claims improperly denied whether pursuant to the Unwritten Policy or otherwise;

J. Consequential economic damages for closed clinics and business interruption;

VERIFICATION

STATE OF NEVADA
COUNTY OF CLARK

BEFORE ME, the undersigned Notary Public and the two (2) undersigned competent witnesses, personally came and appeared:

ROBERT H. ODELL, JR., M.D., PhD.

a person of the full age of majority and a resident and domiciliary of the County of CLARK, State of Nevada, who declared, unto me, the Notary, and the two undersigned competent witnesses as follows:

A. That I, Robert H. Odell, Jr., M.D., hereby certify that I have read the foregoing Verified Complaint; that the statements contained herein are true to the best of my knowledge, except any of those stated to be based upon information and belief as to which I believe such matters to be true.

B. That I, Robert H. Odell, Jr., M.D. Ph.D., as President of Robert Odell M.D. Ph.D. Medical Enterprises, a Nevada Corporation, hereby certify that I have read the foregoing Verified Complaint; that the statements contained herein are true to the best of my knowledge, except any of those stated to be based upon information and belief as to which I believe such matters to be true.

B. I declare under penalty of perjury that the foregoing is true and correct.

IN WITNESS THEREOF, the undersigned notary public, and the two undersigned competent witnesses, along with the affiant, have signed their names herein below on this 17 day of August, 2015, in LAS VEGAS, Nevada.

WITNESSES:
Cindy McEtrlin

Robert H. Odell, Jr., M.D., Ph.D.

Sworn to and subscribed before me this 17 day of August, 2015.

Notary Public, State of Nevada at Large
My Commission Expires: 3/14/18
Affiant is personally known: ___; or produced NV DL# 1607056615 as identification.

JOHN M. MUSCARELLA
Notary Public - State of Nevada
County of Clark
APPT. NO. 98-2477-1
My App. Expires Mar. 14, 2018

K. A Writ of Mandamus requiring defendant to reimburse plaintiff in accordance with the ALJ decisions cited herein;

L. An award of such other temporary and permanent relief as this Court may deem just and proper;

M. The award of costs and reasonable attorney's fees; and

N. Trial by Jury.

Date: August 17, 2015

ROURKE LAW FIRM

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